510(k) **SUMMARY: K100726**
Biolitec Inc.'s Ceralas Fiber-Coupled Diode Laser 980nm Family for an Additional Indication of Use

Submitter's Name, Facility/ Manufacturing Address, Telephone/ Fax Number, Contact Person:

Biolitec Inc.
515 Shaker Road
East Longmeadow, MA 01028
Phone: (413) 525-0600
Facsimile: (413) 526-0611

SEP 15 2010

Contact Person:
Harry Hayes, Ph.D. - Regulatory Consultant, Biolitec Inc. – cell: (413) 250-0779
Email: harry.hayes@biolitec.com
Or
Nancy Foley – Manager of Regulatory Affairs, Biolitec Inc.
Email: nancy.foley@biolitec.com

Date Prepared: March 8, 2010

i. Name of Device and Name/ Address of Sponsor/ Establishment Reg. Number:

Ceralas Fiber-Coupled Diode Laser 980 nm Family

Biolitec, Inc.
515 Shaker Road
East Longmeadow, MA 01028

Establishment Registration Number: 1222625

ii. Common or Usual Name:
Diode Laser

iii. Classification Name:
Laser, Surgical Diode Laser System

iv. Classification Panel:
The General Surgery Devices Branch has classified Diode Lasers as Class II devices pursuant to 21 C.F.R. § 878.4810

v. Predicate Devices:
Ceralas 50W Ceralas D1950 (K072682)
Ceralas G15 532 Frequency Doubled Nd:Yag (K002296)
Quanta System Polysurge Diode Laser Family (K083613)
Quanta System Diode Medical Laser Family (K072034)
INTERmedic Diode Laser family 810nm & 980nm (K053540)

vi. Intended Use/ Indications for Use

	The Ceralas Fiber-Coupled Diode Laser family 980nm (and their delivery accessories used to deliver optical energy) are indicated for use in general surgical applications for incision, excision, ablation, cutting, vaporization, hemostasis, and coagulation of soft tissue contact or non-contact, open or closed endoscopic applications where incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue vaporization, hemostasis and/or coagulation may be indicated.
Added Indication for Use:	Percutaneous Lumbar Disc Decompression/ Diskectomy in soft and cartilaginous tissue.

vii. Technological Characteristics

The Ceralas 980nm family have substantially similar technological characteristics as compared to the Ceralas G15 532nm Frequency-Doubled Nd:YAG laser and the Ceralas D1950 laser, as well as the Quanta System Polysurge 808nm, 980nm & 1950nm laser family, Quanta System Model 30 (808nm & 940nm) laser family and the INTERmedic 810nm & 980nm family.

viii. Performance Data

Performance testing of the Ceralas 980nm family demonstrates no significant difference as compared to the cleared Ceralas G15 532nm Frequency-Doubled Nd:YAG and D1950 lasers.

ix. Substantial Equivalence

The Ceralas 980nm family is as safe and effective for this additional Indication for Use as the Ceralas G15 532nm Frequency-Doubled Nd:YAG and D1950 lasers, the Quanta System Polysurge 808nm, 980nm & 1950nm laser family, the Quanta System Model 30 (808nm & 940nm) laser family and the INTERmedic 810nm & 980nm laser family.

The Ceralas 980nm family has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Ceralas 980nm family and its predicate device raises no new issues of safety or effectiveness. Thus, the Ceralas 980nm family is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 15 2010

Biolitec, Inc.
% Genmarhay BDA
Harry Hayes, Ph.D.
1349 Main Road
Granville, Massachusetts 01034

Re: K100726
Trade/Device Name: Ceralas Fiber-Coupled Diode Laser 980nm Family
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 07, 2010
Received: September 09, 2010

Dear Dr. Hayes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT
The Company's Indications for Use Statement for the Device is provided below.

Indications for Use Statement:

510(k) Number (if known):	*K100726.*
Device Name:	Ceralas Fiber-Coupled Diode Laser Family 980nm (Covering 980nm Models: D15, D25, D50, E15, & E30; HPD100, HPD120, HPD150 & HPD180)
Indications for Use:	The Ceralas Fiber-Coupled Diode Laser family 980nm (and their delivery accessories used to deliver optical energy) are indicated for use in general surgical applications for incision, excision, ablation, cutting, vaporization, hemostasis, and coagulation of soft tissue contact or non-contact, open or closed endoscopic applications where incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue vaporization, hemostasis and/or coagulation may be indicated.
Added Indication for Use:	**Percutaneous Lumbar Disc Decompression/ Diskectomy** in soft and cartilaginous tissue.

Prescription Use ---X --- (Part **21** C.F.R. **801** Subpart D) And/ Or Over-The-Counter Use---------- (**21** C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K100726